



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NOV 21 1988

Re: Ucephan  
Docket No. 88E-0104

Charles E. Van Horn, Esq.  
Deputy Solicitor, Solicitor's Office  
U.S. Patent and Trademark Office  
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,284,647 filed by The Johns Hopkins University pursuant to 35 U.S.C. 156. The human drug product claimed by the patent is Ucephan (sodium phenylacetate and sodium benzoate), New Drug Application (NDA) 19-530.

In the May 11, 1988 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). That notice provided that on or before November 11, 1988, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i), for a determination of whether the patent applicant acted with due diligence during the applicable regulatory review period. 53 Fed.Reg. 91, at 16786-87.

The 180-day period for filing a due diligence petition pursuant to the notice regarding Ucephan has expired, and FDA has received no such petition. FDA, therefore, considers its determination of the regulatory review period for this product to be final.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Donald J. Bird  
Cushman, Darby and Cushman  
11th Floor  
1615 L Street N.W.  
Washington, D.C. 20036